Emergency Bag/Bellows Breathing Assist Device: Scope and Specifications

In the event of a large number of COVID-19 cases happening in India and similar developing countries, the existing number of ventilators is likely to be insufficient to cater to patients with compromised lung functions. This scenario has already been observed in Italy, Spain, etc.

As COVID-19 patients over 60 are especially at risk, supplementing their lung function with a mechanical ventilator becomes vital to ensure their recovery.

Scope:
Like many others across the globe, this group proposes to put together a DIY open source and very basic mechanical breathing assist device that may be used in hospital settings to help solve ventilator shortages. The design, code, list of parts and suppliers, diagrams and all information required to make these devices will be available to everyone.
Since this is a DIY initiative regulatory compliance is not within the scope.

At a basic level, the device has to accomplish the following:

1. Deliver oxygenated air to the patient to overcome decreased lung function.
2. The concentration of O2 in the inlet air is called FiO2, and an FiO2 of 1.0 means a 100% O2. The device user should be able to control the FiO2 based on the patient's requirement.
3. The O2 in the patient's blood is measured by SpO2, and is a measure of how the lungs are functioning to take O2 from the air and oxygenate blood. Ventilators may also track SpO2 and accordingly modify pumping parameters.
4. Pressure of air going inside has to be tracked.
5. Pressure inside the lungs has to be tracked to ensure abnormal pressure is not created.
6. Flow has to be measured to ensure the right volume of air is being delivered.

Specifications:

1. Target air flow: 60-100 LPM
2. Flow and pressure tunable to cater to target COVID-19 patients (children and adults with pre-existing conditions as well as senior citizens)
3. Pressure measured at patient connection port: settings 4, 8, 12, 16 & 20 cm H2O
4. Sensitivity: -2cm H2O
5. Noise levels less than 40DB
6. Respiratory rate: 10-15 breaths per minute
7. FiO2 levels to be reached: 1.0 (100%)
8. Sigh rate: 1-2 times per minute with VT =20ml/kg
9. PEEP: 0-5 cm H2O
10. Separate connections for electrical and electronic components
11. Redundancy of critical components like pumps to ensure continuity
12. Alarms to alert upon failure if a critical parameter like SpO2 is affected.

Verification Requirements:

Ideally at all operational steps or at a minimum for corner cases3

1. Tidal Volume/ Air flow rate (static/tuning)
2. Pressure levels (static/tuning)
3. BPM rate
4. Emergency shut off
5. Pressure relief functionality (if used)
6. Alarms
    a. Over Pressure
7. Electrical isolation form all user contact points (if applicable)
8. Power backup/run time/battery life
9. Fixing and Removal procedures of mask/patient support accessories
10. Storage and Cleanliness procedures for consumables/tubes - During usage, storage, or transportation (ensure no unintentional infection to patient)
11. Tering of Ambu-bag during operation/assembly/storage/transportation

Bill of Material for Bag/Bellows DIY Ventilator

	Part	Quantity	Price	Source
1	Ambu-bag (silicon)	3		
2	Bellow/diaphragm pump	3		
3	Pressure sensors			
4	Solenoid Valves			
5	D Lite sensor venturi			
6	Envotec OOM2O2 O2 sensor			
7	Arduino Duo			
8	RPi Zero/3b+			
9	SpO2 sensor Ble type			
10	Overpressure Relief Valve			
11	Recircling, tuning vlave			
12	Orifice plate			

13	Exhaust throttle Valve			
14	Centrifugal blower			
15	HEPA outlet			
16	SFM3300-D, Air Flow Sensors	2		Mouser.in (403-SFM3300-D)
17	Tubing & Accessories, including connectors/glands			
18	Alarm beepers, SBS12LMMVPC			Mouser.in (539-SBS12LMMVPC)

References:

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5. https://www.ncbi.nlm.nih.gov/books/NBK441924/
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8. https://cdn.hackaday.io/files/1701897281366176/Husseini%202010%20-%20Design%20and%20Prototyping%20of%20a%20Low-cost%20Portable%20Mechanical%20Ventilator%20-%20MIT.pdf
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